

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division**

Combe Incorporated,)	
)	
Plaintiff,)	
)	
v.)	No. 1:17-cv-935 (TSE/MSN)
)	
Dr. August Wolff GmbH & Co.)	
KG Arzneimittel,)	
)	
Defendant.)	

**REPLY MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT’S PARTIAL
MOTION TO DISMISS COUNTS II–VI FOR FAILURE TO STATE A CLAIM
PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(6)**

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INTRODUCTION

Combe's opposition brief confirms that the Court should grant Wolff's partial Rule 12(b)(6) motion because Combe has not and cannot plead any facts showing that Wolff has ever used the VAGISAN mark in the sale, advertising or transportation of any goods in commerce as required to state a claim for trademark infringement, unfair competition, or dilution.

Combe improperly conflates evidence of statutorily mandated intent to use with the use in commerce required for infringement claims. Indeed, Combe has not been able to plead any specific sale by Wolff of VAGISAN products in the United States. Instead, Combe claims that Wolff's passive European website www.vagisan.com is sufficient "use" even though Wolff does not sell its products on the site. However, the Fourth Circuit has held that mere use of a mark on website is not "use" of a mark for purposes of an infringement claim unless accompanied by U.S. sales of products or links to third-party sellers. Combe grossly mischaracterizes the TTAB record by suggesting that Wolff is on the verge of launching its VAGISAN products in the United States. But the TTAB testimony contains un rebutted evidence that Wolff's intent to sell has been put on hold pending the outcome of Combe's appeal. Moreover, the testimony only shows communications between Wolff and *potential* U.S. distributors and consultants that occurred *five or six years ago*. Wolff has not even decided how its VAGISAN mark would be displayed if its products are ever sold here, where the products would be sold and advertised, or the type of products that would be sold. Like other filers of intent to use trademark applications, Wolff has deferred selling products pending the final approval by the PTO, to avoid subjecting itself to an infringement claim in a U.S. court.

To adjudicate a trademark infringement claim without actual use of a mark by the defendant, a court must be shown evidence of imminent or impending plans by the defendant to launch a product or service under an infringing mark. Combe has not and cannot cite a single

case where a court adjudicated an infringement claim where a defendant has provided sworn testimony that it has not and will not use the allegedly infringing mark in U.S. commerce while a TTAB appeal is pending.

In the Fourth Circuit, the issue of likelihood-of-confusion for infringement purposes is not ripe for adjudication until a defendant actually uses its mark in U.S. commerce. Otherwise, a court cannot make the requisite assessment as to how the consuming public actually encounters the parties' marks in the marketplace. Those facts cannot be presented here because Wolff is not using its VAGISAN mark in the United States. It would be manifestly unjust to force Wolff to defend itself against a trademark infringement claim when the relevant facts are merely hypothetical. Adjudicating such a claim in this case would be a waste of judicial resources.

Combe's arguments are based on the false assertion that the likelihood-of-confusion analysis is the same in both a TTAB proceeding and a civil action for infringement. In a TTAB proceeding involving an intent to use application, the TTAB does not consider the marketplace conditions. Instead, the TTAB presumes that an Applicant's goods are sold in the same channels of trade and to the same customers who purchase the Opposer's goods. The TTAB also only considers the similarity of the marks and goods as they appear in the application and registration, without consideration as to differences in packaging or trade dress or the precise nature of the goods that are actually sold.

By contrast, in a civil action for infringement, the marketplace conditions in which the parties' marks and goods are sold is paramount. A court cannot presume that the parties' trade channels, customers, or goods are similar, but must consider evidence of how the parties' marks are actually used in the marketplace. Because Combe cannot plead or prove facts that do not yet exist, Combe cannot state valid claims for infringement, dilution or unfair competition.

Accordingly, Counts II through VI of the Complaint should be dismissed for failure to state a claim pursuant to Rule 12(b)(6).

LEGAL STANDARD AND RELEVANT BACKGROUND

In reviewing a Rule 12(b)(6) motion, the Court cannot accept as true “allegations that contradict matters properly subject to judicial notice or by exhibit.” *Veney v. Wyche*, 293 F.3d 726, 730 (4th Cir. 2002); *see also id.* (“We are not required ... to accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences.”) (internal quotation marks and citation omitted).¹

Combe’s Complaint and its opposition brief are rife with mischaracterizations, unwarranted assumptions of fact, and incorrect statements that contradict the TTAB record and the exhibits filed with this Court. The Court cannot accept such unfounded allegations as true in reviewing Wolff’s Rule 12(b)(6) motion.

First, Combe’s allegation in the Complaint that Wolff used the VAGISAN mark in U.S. commerce (ECF No. 1, ¶ 29) is directly contradicted by the record on appeal which contains Wolff’s un rebutted sworn testimony that it has never sold and will not sell VAGISAN products in the United States until the TTAB appeal is resolved.

¹ Contrary to Combe’s contention, Wolff’s Rule 12(b)(6) motion to dismiss was timely filed because Wolff has not yet filed an Answer with regard to the claims it seeks to dismiss (Counts II-VI). Rather, Wolff merely answered Count I (the TTAB appeal), but filed a motion to dismiss Counts II-VI for lack of personal jurisdiction. Because Wolff has not yet answered Counts II-VI, its right to file a Rule 12(b)(6) motion to dismiss those claims for failure to state a claim is preserved. *Godlewski v. Affiliated Computer Servs., Inc.*, 210 F.R.D. 571, 572 (E.D. Va. 2002). But even if the Rule 12(b)(6) motion was *arguendo* untimely, which it was not, “Rule 12(h)(2) provides that the defense as set forth in Rule 12(b)(6) may be raised by motion for judgment on the pleadings under Rule 12(c) or at trial on the merits.” *Williams v. Equity Holding Corp.*, 498 F. Supp.2d 831, 839 (E.D.Va. 2007) (citations omitted). “Thus, even if defendants’ motion to dismiss for failure to state a claim was untimely, this court would simply construe the motion under Rule 12(c) and decide it under the same standard as Rule 12(b)(6).” *Id.*

Q. And so Dr. Wolff has not used the Vagisan product in the United States; is that correct?

A. We have not sold them so far...

Q. Do you have any business plans to use the Vagisan product in the United States?

A. Yes, we have just been in contact with two companies here in the U.S., but ***we have put this on hold for the reason like I just told you, we don't know whether we can use our brand***

TTAB Dep. of Angela Thevessen, Feb. 11, 2016, ECF No. 28-2 at 34:5-17) (emphasis added).

The reason Wolff does not know whether it can use its VAGISAN brand in the United States is the pendency of Combe's TTAB appeal in this Court. *See* Reply Decl. of Angela Thevessen, ECF 20-1 at ¶ 9 ("Wolff will not sell its products under the VAGISAN mark in the United States until this Court affirms the Trademark Trial and Appeal Board finding that there is no likelihood of confusion between the marks VAGISAN and VAGISIL.").

Combe's opposition brief grossly mischaracterizes Wolff's intent to sell VAGISAN products in the future as evidence that such a sale is impending or imminent. While deliberately omitting any details regarding dates, Combe claims that "Wolff has had discussions with U.S. distributors, including a prominent convenience/drug store chain 'extremely interested in selling our Vagisan.'" ECF No. 28 at 6. In fact, the record on appeal shows that the referenced meeting occurred *six years ago*, in March 2012, and was unsuccessful. *See* Thevessen Dep.² 16:22-25; 19:12-13 ("In the beginning of 2012, we have been approached by a U.S. American company called LIL Drugstore which were extremely interested in selling our Vagisan ... [but] we did not finalize this business relationship"). The March 2012 meeting "was [Wolff's] only appointment

² "Thevessen Dep." refers to the Deposition of Angela Thevessen dated October 19, 2016 in *Combe Incorporated v. Dr. August Wolff GmbH & Co. KG Arzneimittel*, Opposition 91209708, in the United States Trademark Trial and Appeal Board, excerpts of which are attached as Exhibit 1 to the Reply Declaration of Ross Q. Panko being filed concurrently.

with a potential distributor.” Thevessen Dep. 33:18-19. After the March 2012 meeting, Wolff told Lil Drugstore “we do not want to enter into a business relationship.” *Id.* at 42:7-9. Wolff has not had any further meetings with Lil Drugstore since the failed meeting in 2012, and has put its plans to secure a U.S. distributor on hold because of the TTAB opposition filed by Wolff. *See* Thevessen Dep. 33:21-25 (“[I]n 2013, we have received the opposition of Combe, and this is when the whole process slowed down a little because we do not know whether we can enter the U.S. market with our brand Vagisan.”).

Combe then misleadingly claims that “Wolff retained a U.S.-based consultant, to whom it sent slides regarding ‘the eventual sale of the Vagisan product in the U.S.’ and who presented that information at a ‘JP Morgan Conference Meeting to take place in the United States.” ECF No. 28 at 6. Again, Combe neglects to mention that the subject e-mail between Wolff and Thallo Bioscience was sent over *five years ago*, on January 2, 2013. ECF No. 19-3 at 32. Likewise, Combe misleadingly refers to e-mail correspondence with “independent contractors” in the U.S., but the exhibit it cites merely refers to the same Thallo Bioscience e-mail referenced above, from five years ago, and two e-mails dated November 29, 2012 and February 19, 2013 to Granzer Consulting in connection with Wolff’s FDA application. ECF No. 19-3 at 40-45.

Combe also mischaracterizes Ms. Thevessen’s testimony concerning unauthorized U.S. sales of VAGISAN products via Amazon.com. Wolff does not “**embrace**” those sales as claimed by Combe, and Ms. Thevessen provided un rebutted evidence that Wolff did not place the products on Amazon.com and did not know who was selling them. Thevessen Dep. 43:25-44:4: (“Q. Dr. Wolff, do they have any involvement of placing the products on the Amazon website for sale in the United States? A. No, we haven’t.”); *id.* at 42:23-25 (“It is available on Amazon through we believe, we don’t know for sure, but we believe German pharmacies.”); ECF No. 6-1

¶ 15 (“Wolff has not sold VAGISAN products in the United States via Amazon.com, and has not authorized or directed anyone, including distributors, to sell VAGISAN products in the United States via Amazon.com.”).

Combe previously alleged that a German pharmacy called Pelikan Apotheke sold VAGISAN products in the United States, but both Wolff and Pelikan Apotheke confirmed that Wolff never authorized it to sell in the United States and that Pelikan Apotheke in fact had never sold VAGISAN products in the U.S. ECF 20-1 ¶¶ 5-6 & Ex. 1 (“Wolff has not authorized or directed anyone, including Pelikan Apotheke, to sell or ship VAGISAN products via or in the United States [and] Pelikan Apotheke has never sold Wolff’s VAGISAN products in the United States.”) Without contradicting the record on appeal and violating Rule 11 of the Federal Rules of Civil Procedure, Combe cannot plead that Wolff has sold or authorized the sale of VAGISAN products via Amazon.com or anywhere else in the United States.

Combe then alleges that Wolff has sold VAGISAN products to U.S. consumers via its website www.vagisan.com (ECF No. 28 at 5), but this conclusory allegation contradicts the record on appeal and is unsupported by any specific facts. ECF No. 6-1 ¶ 13 (“Wolff does not sell VAGISAN products to the United States via Wolff’s website www.vagisan.com”).

Combe also claims that merely because the FDA has now approved Wolff’s VAGISAN product, Wolff is “**all set**” to commence sales of VAGISAN products in the United States. But that assertion also mischaracterizes Ms. Thevessen’s testimony in the record below. She testified that the lack of FDA approval was only one of two reasons why VAGISAN sales were on hold in the United States – the other reason being the pendency of Combe’s TTAB proceeding and appeal. ECF No. 28-2 at 34:11-21 (“Yes, we have just been in contact with two companies here in the U.S., but we have put this on hold for the reason like I just told you, *we don’t know*

whether we can use our brand, and the second reason is that Dr. August Wolff is not FDA conformed, the whole company, and we are right now in the process of getting—yeah, making it FDA conformed so once they audit us we are all set.”) (emphasis added). Ms. Thevessen was not asked what she meant by “all set,” but plainly she did not mean that Wolff would immediately begin selling VAGISAN upon receipt of FDA approval. And she has subsequently confirmed this in her declarations. *See, e.g.*, Thevessen Dec. Dated January 22, 2018, ¶ 5.

Combe misleadingly asserts that Wolff “has already determined the volume of VAGISAN products it wants to sell in the U.S.” ECF No. 28 at 7. But the deposition excerpt quoted by Combe from the record below merely describes the general approach that Wolff takes when it enters a new market. ECF 19-2, Thevessen Dep. at 35:17-36:3. Wolff has not made any final determination as to the volume of VAGISAN products it may ship to the United States if in fact the Court affirms the TTAB ruling. Thevessen Dec. Dated January 22, 2018, ¶ 11.

Combe also incorrectly claims that Wolff has already determined the type of products it would sell in the United States under the VAGISAN mark, but it has no basis for making this incorrect assertion. The Thevessen deposition excerpt cited by Combe merely states that moisturizing cream is the product Wolff “would like to” sell in the United States. ECF No. 28 at 7. And the excerpt concerning the product description in Wolff’s FDA application merely concerns the medical device class for the moisturizing cream. *Id.* Wolff has not made any final determination concerning the precise products it will sell under the VAGISAN or even whether the product will be sold over the counter or by prescription. Thevessen Dec. Dated January 22, 2018, ¶ 12.

In addition, Wolff has not decided how its VAGISAN mark will be displayed on packaging and in advertising if it is sold in the United States. *Id.* ¶¶ 6, 8. Wolff has likewise not

determined where and how its VAGISAN products would be advertised and sold in the United States, including whether they would be sold through drug stores, or mass merchandising stores or whether sales would be limited to hospitals, clinics or other health care providers. *Id.* ¶ 13.

ARGUMENT

A. Combe Has Failed to Plead “Use” of the VAGISAN Mark By Wolff As Required To State a Claim for Trademark Infringement, Unfair Competition, and Dilution.

Combe acknowledges that the statutes on which it bases Counts II through VI of the complaint require pleading “use in commerce.” It claims that the relevant “use” for infringement and dilution purposes encompasses broader uses than what is set forth in 15 U.S.C. § 1127. (ECF 28 at 11-13). However, Combe cites no Fourth Circuit authority for this position, and the portion of the Second Circuit’s *Rescuecom* decision that it cites (the Appendix) is dictum. *See Rescuecom Corp. v. Google, Inc.*, 562 F.3d 123, 138 (2d Cir. 2009). In fact, the binding portion of *Rescuecom* favors Wolff, as the court applied the “use in commerce” definition set forth in 15 U.S.C. § 1127 to conclude that Google’s use of the plaintiff’s “RESCUECOM” trademark as an advertising keyword constituted “use in commerce” for infringement purposes:

Google displays, offers, and sells Rescuecom's mark to Google's advertising customers when selling its advertising services. In addition, Google encourages the purchase of Rescuecom's mark through its Keyword Suggestion Tool. Google's utilization of Rescuecom's mark fits literally within the terms specified by 15 U.S.C. § 1127. According to the Complaint, Google uses and sells Rescuecom's mark “in the sale ... of [Google's advertising] services ... rendered in commerce.” § 1127.

See id. Combe has not cited any Fourth Circuit decision that endorsed the dictum of the *Rescuecom* decision.

In the Fourth Circuit, to show “use of a mark” for infringement purposes, a plaintiff must plead and prove that the defendant has actually sold or advertised goods bearing the mark in commerce to U.S. consumers, or provided links to third-party commercial websites that are

selling goods to U.S. consumers. *See, e.g., People for Ethical Treatment of Animals v. Doughney*, 263 F.3d 359, 366 (4th Cir. 2001).³

As detailed below, Combe has not and cannot plead any facts showing that Wolff has used the VAGISAN mark in the sale, advertising or transportation of goods in commerce or otherwise engaged in activities sufficient to give rise to infringement claims in a U.S. court.

1. Wolff’s Display of the VAGISAN Mark on its Website Is Not “Use” for Purposes of a Lanham Act Claim.

Combe incorrectly claims that Wolff’s display of the mark VAGISAN on its passive European website www.vagisan.com constitutes “use” of the VAGISAN mark in the United States. However, the mere use of a mark on a website does not give rise to an infringement claim. *See PETA*, 263 F.3d at 365–66. Instead, the defendant’s website must either sell infringing goods under the mark to U.S. consumers, connect the user to another’s services or goods, or otherwise specifically target U.S. consumers. *See PETA*, 263 F.3d at 366 (affirming lower court finding of infringement when “[Defendant’s] web site provides links to more than 30 commercial operations offering goods and services”).

The *PETA* decision cited by Combe is not applicable here. In *PETA*, the U.S.-based defendant created a website entitled “People Eating Tasty Animals,” to induce U.S. consumers to buy “fur, leather, magazines, clothing, equipment and guide services.” *People for Ethical Treatment of Animals, Inc. v. Doughney*, 113 F. Supp. 2d 915, 919 (E.D. Va. 2000), *aff’d*, 263 F.3d 359 (4th Cir. 2001). The Fourth Circuit affirmed by finding the defendant used plaintiff’s

³ Combe’s infringement and unfair competition claims require Combe to satisfy five elements: (1) that the plaintiff possesses a mark; (2) that the defendant used the mark; (3) that the defendant’s use of the mark occurred “in commerce”; (4) that the defendant used the mark “in connection with the sale, offering for sale, distribution or advertising” of goods or services; and (5) that the defendant used the mark in a manner likely to confuse consumers. *Lamparello*, 420 F.3d 309, 313 (4th Cir. 2005) (citations omitted).

mark “in connection with” **the sale** of goods or services and thus infringed the mark in providing links to 30 commercial websites. *PETA*, 263 F.3d at 365-66.

There are no such facts here. Wolff does not sell VAGISAN products via its website nor does it provide any links to third parties that sell the products to the United States.

The *Lamparello* case cited by Combe is likewise distinguishable and does not help Combe. There, the defendant created a parody website entitled www.fallwell.com to comment on Jerry Falwell. *Lamparello*, 420 F.3d at 315. The parties agreed that the defendant had not sold “goods or services on his website.” *Id.* at 311. Ultimately, the Fourth Circuit did not reach the issue of whether the defendant’s use of the mark “Fallwell” was a “use in commerce” for infringement purposes because it affirmed the lower court’s decision of non-infringement on the grounds that there was no likelihood of confusion given the stark differences in the appearance and content of the parties’ respective websites. *Id.* at 314-15.

Consequently, the Fourth Circuit cases cited by Combe support Wolff, and *PETA* underscores that the mere use of a mark on a website, without accompanying sales or links to U.S. sites selling products under the mark, is not “use in commerce” for infringement purposes.

2. Wolff’s Alleged “Steps Toward Entering the U.S. Market” Are Not Sufficient to State a Claim for Infringement, Unfair Competition, and Dilution.

Combe falsely claims a defendant’s mere “plans toward launching use of a mark are also sufficient for stating infringement, unfair competition, and dilution claims.” ECF No. 28 at 15. And it also incorrectly asserts that courts do not require a defendant’s potential use of a mark to be “imminent and impending” to adjudicate an infringement claim. ECF No. 28 at 2. In fact, however, numerous decisions have employed the “imminent and impending” standard. *See, e.g., Maritz, Inc. v. Cybergold, Inc.*, 947 F. Supp. 1328, 1335 (E.D. Mo. 1996) (“A Lanham Act claim can exist even before a defendant actually opens the business, so long as the acts of defendant are

imminent and impending”) (emphasis added); *Essie Cosmetics, Ltd. v. Dae Do Int’l, Ltd.*, 808 F. Supp. 952, 957 (E.D.N.Y. 1992) (“In a trademark infringement action, a court may grant injunctive relief ‘even before defendant actually opens the business,’ so long as the threatened act of defendant is ‘**imminent and impending.**’”) (emphasis added). Some courts do not use the specific phrase “imminent and impending” in their analysis of this issue, but all of them require evidence that the defendant is truly on the verge of using its mark in U.S. commerce. Wolff’s conduct plainly does not meet this standard because it has affirmatively stated it will not use the mark pending the outcome of the TTAB appeal and thus far it has not made any such use.

The cases cited by Combe are plainly distinguishable. For example, in *AARP*, the defendant was “**actively seeking** licensees to publish a magazine” and had “conduct[ed] extensive analysis of the publishing industry” in preparation for the launch of such product. *AARP v. 200 Kelsey Assoc., Inc.*, No. 06 Civ. 81(SCR), 2009 WL 47499, at *9 (S.D.N.Y. Jan. 8, 2009) (emphasis added). Combe disingenuously claims *AARP* is analogous, but it is not because Wolff’s only meeting with a potential distributor occurred *six years ago*, and was a one-time meeting that was not successful. Wolff does not have any U.S. distributors and its plans are on hold pending the outcome of the TTAB appeal. Thevessen Dec. Dated Jan. 22, 2018, ¶¶ 9-10.

Likewise, *Capital One* bears no resemblance to the instant case because there, the declaratory judgment plaintiff was already using the infringing mark in the United States. *See Capital One Fin. Corp. v. Drive Fin. Servs., LP*, 434 F. Supp. 2d 367, 374 (E.D. Va. 2006) (“Plaintiff displayed materials containing the DriveOne mark to a large, national automobile dealer[,] displayed a poster for its DriveOne program at a booth at the NADA convention[,] [and] visited with a number of dealers to discuss its DriveOne program, during which time Plaintiff showed the dealers the DriveOne brochure.”). By contrast, Wolff has not used its mark in the

United States. Instead, Wolff had a single, unsuccessful meeting with a potential U.S. distributor, in Germany, in 2012. Wolff's e-mail correspondence with two other U.S. companies occurred in 2012 and 2013, but did not result in use of the VAGISAN mark in the United States or promotion of VAGISAN products in the United States as was the case in *Capital One*.

Maritz is similarly distinguishable because there, the defendant was using its website and trademark to contact U.S. consumers and develop a mailing list, and was thus using the mark for infringement purposes. *Maritz*, 947 F. Supp. at 1335. Combe alleges that Wolff's conduct is no less "imminent and impending" than the defendant's plans in *Maritz*. ECF No. 28 at 19. But this is a baseless claim because Wolff's website never "invited U.S. consumers" to buy the VAGISAN products from the website and Wolff has never sold VAGISAN products on the website. Combe's statement that Wolff's VAGISAN products "could easily have been sold in the United States" after FDA approval is irrelevant and ignores Wolff's sworn declaration that it will not sell those products until the TTAB appeal is resolved. Accordingly, the facts of the instant case stand in stark contrast to *Maritz*.

In *De Simone*, the court held that the defendant's use of the mark VISBIOME on its website constituted use of the mark for infringement purposes, but only because "**actual sales of VISBIOME are imminent.**" *De Simone v. VSL Pharms., Inc.*, 133 F. Supp. 3d 776, 797 (D. Md. 2015) (emphasis added). Likewise, in *PDK Labs, Inc. v. Proactive Labs, Inc.*, 325 F. Supp. 2d 176, 180 (E.D.N.Y. 2004), the defendant was actually using the infringing mark to promote its goods at U.S. trade shows and on its website.⁴ Wolff has engaged in no such conduct.

⁴ The *Reebok* and *Nintendo* decisions cited by Combe are inapplicable as both of those cases involve the concept of extraterritorial injunctions, which is not an issue in this case. ECF No. 28 at 19-20. Combe's Complaint has not requested an extraterritorial injunction, nor is there any basis for the court to grant one since Combe cannot plead that Wolff activities in Europe have had any significant effect on U.S. commerce.

The cases cited by Combe are thus distinguishable, as Wolff is not using the VAGISAN mark in U.S. commerce nor is it on the verge of launching VAGISAN products in this country.

3. The Mere Filing of an Intent-to-Use Trademark Application Does Not Give Rise to a Claim for Infringement.

Combe makes the conclusory allegation that the cases cited by Wolff on the effect of intent-to-use U.S. trademark applications are inapplicable because “Wolff’s actions have gone far beyond the ‘mere filing’ of an intent-to-use trademark application.” ECF No. 28 at 20.

However, Combe has cited no facts showing an imminent or impending intent to launch VAGISAN products in the United States, and it was never able to rebut the evidence in the record on appeal showing that Wolff’s plans are on hold. Wolff’s intent-to-use cases are thus directly on point. *See Macia v. Microsoft Corp.*, 152 F. Supp. 2d 535, 539 (D. Vt. 2001) (“The only alleged use of the mark is Intuit’s filing of an ITU trademark application. ***Unless and until Intuit uses the mark in the course of trade, to identify actual goods for sale or transport, it cannot be subject to suit for trademark infringement under § 1125(a)***”) (emphasis added).⁵

Accordingly, Wolff’s mere filing of an intent-to-use application without actual use of the mark in U.S. commerce does not give rise to a claim for infringement or unfair competition.

⁵ *See also Omega S.A. v. Omega Eng’g, Inc.*, 396 F. Supp. 2d 166, 174 (D. Conn. 2005) (“Neither the application for a trademark registration nor the existence of a pending trademark application give rise to a claim of trademark infringement or false designation of origin.”); *Office of Strategic Services, Inc. v. Sadeghian*, 528 F. App’x 336, 346 (4th Cir. 2013) (“The trademark registration, however, does not change the fact that OSS failed to show that the Sadeghian Parties actually used the mark. A cause of action for trademark infringement or unfair competition under the Lanham Act requires a plaintiff to prove, *inter alia*, that the defendant used the mark.”); *see also Marshall Tucker Band, Inc. v. M T Indus., Inc.*, 238 F. Supp. 3d 759, 764–65 (D.S.C. 2017), *amended on other grounds*, 2017 WL 1469356 (Apr. 25, 2017) (“[r]egistration of a trademark, standing alone, is insufficient to constitute a use in commerce as required to state a claim under the Lanham Act.”).

4. The Likelihood of Confusion Factors Are Not Ripe for Adjudication and It Would Be Inefficient and Prejudicial to Wolff to Adjudicate the Infringement and Unfair Competition Claims Now When The Relevant Facts Do Not Exist.

Combe incorrectly claims that this case is ripe for adjudication despite Wolff's non-use of the mark because "courts can and do adjudicate [the] merits of a likelihood-of-confusion claim based on defendant's plans to commence use of the mark—before all the individual likelihood-of-confusion factors are fully fleshed out." ECF No. 28 at 22. Combe's assertion and the cases it cites are inapplicable because the Fourth Circuit has emphasized that unless and until a defendant uses its mark, the court cannot properly analyze the likelihood of confusion. *See Carefirst of Md., Inc. v. First Care, P.C.*, 434 F.3d 263, 267 (4th Cir. 2006) ("[W]e look to how the two parties *actually use their marks in the marketplace* to determine whether the defendant's use is likely to cause confusion.") (citing *What-A-Burger of Va., Inc. v. Whataburger, Inc.*, 357 F.3d 441, 450 (4th Cir. 2004) (emphasis added))⁶.

Combe's reliance on the Ninth Circuit's *LaQuinta* decision is misplaced because there, the defendant was actually using the subject mark to advertise its hotels via U.S. websites, including Expedia.com and Orbitz.com. *See LaQuinta Worldwide LLC v. Q.R.T.M., S.A. de C.V.*, 762 F.3d 867, 872 (9th Cir. 2014). The court thus knew what the defendant's mark was, that it would offer hotel services, where the hotels would be located, and how they would be advertised.

⁶ *See also Calvin Klein Cosmetics Corp. v. Lenox Labs., Inc.*, 815 F.2d 500, 504 (8th Cir. 1987) ("A realistic evaluation of consumer confusion must attempt to recreate the conditions in which buying decisions are made, and the court should try to determine not what it would do, but what a reasonable purchaser in market conditions would do."); *Malletier v. Burlington Coat Factory Warehouse Corp.*, 426 F.3d 532, 538 (2d Cir. 2005) ("[T]he Lanham Act requires a court to analyze the similarity of the products in light of the way in which the marks are actually displayed in their purchasing context."); *Kemp v. Bumble Bee Seafoods, Inc.*, 398 F.3d 1049, 1054 (8th Cir. 2005) ("[O]ur comparison of the similarity between marks and products must occur in a context that recognizes how consumers encounter the products and how carefully consumers are likely to scrutinize the marks.").

Similarly, in *Maritz*, a Missouri federal court case, the defendant was already using his mark on his website to solicit consumers and develop a mailing list, and it was known what the mark would be, who the customers would be and where the service would be offered. *Maritz*, 947 F. Supp. at 1339.

By contrast, in this case, the facts concerning the likelihood of confusion factors are unknown because Wolff is not yet selling the VAGISAN products in the United States nor has it determined *inter alia* how its marks may be displayed on packaging or advertising nor has it decided where the products will be sold, or the nature of the products.

The fact that the TTAB adjudicated the issue of likelihood of confusion in the parties' opposition proceeding does not mean the likelihood of confusion factors are ripe for adjudication in a civil action for infringement. Indeed, the analysis of the likelihood of confusion is very different in a TTAB proceeding as compared to a civil action. The TTAB does not consider the marketplace conditions with regard to several of the factors. As explained by Professor McCarthy:

In determining likelihood of confusion in an opposition, it is the mark as shown in the application and as used on the goods described in the application which must be considered, not the mark as actually used by applicant. ... This is the rule because an opposition does not determine anything other than the applicant's right to a federal registration of the mark as defined in the application and as used on the goods or services listed in the application. It does not matter how the mark will actually appear in context as it is used in the marketplace on labels, in advertising and on web pages, for that is not the question in an opposition.

McCarthy on Trademarks and Unfair Competition § 20:15 (4th ed. 2017).

Accordingly, the TTAB presumes that each party's goods are sold in the same channels of trade to the same customers, based on the face of their respective application and registration. *See Cunningham v. Laser Golf Corp.*, 222 F.3d 943, 948 (Fed Cir. 2000) (affirming TTAB decision that where application is unrestricted, "we must deem the goods to travel in all

appropriate trade channels to all potential purchasers of such goods”); *see also In re Viterro*, 671 F.3d 1358-1361-62 (Fed. Cir. 2012). The TTAB also only considers the similarity of the marks and goods as they appear in the application and registration, without consideration of how the marks are actually displayed in the marketplace, or the nature of the goods that are actually sold. *See Cunningham*, 222 F.3d at 948 (“[I]t is irrelevant that Cunningham has a particular display for his mark in commerce, and the Board was correct to ignore those features”); *Stone Lion Capital Partners, L.P. v. Lion Capital LLP*, 746 F.3d 1317, 1325 (Fed. Cir. 2014) (analysis of goods in TTAB proceeding limited to face of respective application and registration).

By contrast, in a civil action for infringement, the marketplace conditions in which the parties’ marks and goods are sold are paramount. The court cannot presume that the parties’ trade channels, customers, or goods are similar, but must consider evidence of how the parties marks are actually used in the marketplace. *See Carefirst of Md., Inc.*, 434 F.3d at 271 (“To determine whether two marks are similar, ‘we must examine the allegedly infringing use ***in the context in which it is seen by the ordinary consumer.***’”) (emphasis added)). That evidence does not exist here, and thus the likelihood-of-confusion factors are not ripe for adjudication with regard to Combe’s infringement and unfair competition claims.

A review of the individual likelihood-of-confusion factors⁷ illustrates the lack of relevant evidence to adjudicate this issue:

⁷ In the Fourth Circuit, courts consider nine factors in determining likelihood of confusion: (1) the strength or distinctiveness of the plaintiff’s mark as actually used in the marketplace; (2) the similarity of the two marks to consumers; (3) the similarity of the goods or services that the marks identify; (4) the similarity of the facilities used by the markholders; (5) the similarity of advertising used by the markholders; (6) the defendant’s intent; (7) actual confusion; (8) the quality of the defendant’s product; and (9) the sophistication of the consuming public.

Similarity of the Parties' Facilities. Combe claims it sells its VAGISIL products via “mass merchandizing stores, drug store chains, grocery stores, and retailers, such as Wal-Mart, CVS, Target, Walgreens, Rite-Aid, Kroger, Publix, and Amazon.com.” ECF No. 28 at 24. However, Wolff has not determined the trade channels through which it might sell VAGISAN products in the United States. Thevessen Dec. Dated Jan. 22, 2018, ¶ 13. For example, the trade channels could be hospitals and health care providers as opposed to retail stores. *Id.* And Wolff does not already sell VAGISAN products via Amazon.com as alleged by Combe, and any products sold on that site were never authorized by Wolff. ECF No. 6-1. In a civil action, unlike a TTAB proceeding, the Court cannot presume that Wolff’s products will be sold in the same channels of trade as those of Combe. Instead, it is the plaintiff’s burden to prove the similarity of the respective trade channels based on actual use of the marks in the marketplace. Accordingly, the similarity of the parties’ facilities factor is not ripe for adjudication.

Similarity of the Parties' Advertising. Combe claims the facts concerning this factor are established merely because Wolff is already using a website (www.vagisan.com) to promote its products in Germany and Europe. That assertion is wrong because as stated *supra*, Wolff’s website does not target U.S. consumers and, in fact, VAGISAN products are not sold via the www.vagisan.com website. ECF No. 20-1. Combe is doing no advertising in the U.S. and no facts exist to evaluate this factor in a U.S. action.

Further, in analyzing the “similarity of facilities” and “similarity of advertising” factors, courts in the Fourth Circuit assess the actual facilities and advertising methods used by the parties in U.S. commerce. Minute details of the parties’ actual uses are often highly relevant.

George & Co. v. Imagination Entm't Ltd., 575 F.3d 383, 393 (4th Cir. 2009) (citing *Pizzeria Uno Corp. v. Temple*, 747 F.2d 1522, 1527 (4th Cir. 1984); *Sara Lee Corp. v. Kayser-Roth Corp.*, 81 F.3d 455, 463-64 (4th Cir. 1996)).

For example, in *CareFirst of Md., Inc.*, the court found the respective facilities different where “First Care displays its mark on the outside of each of its doctors' offices” but “CareFirst's mark enjoys no similarly prominent placement with its participating providers.” *CareFirst of Md.*, 434 F.3d at 273. Here, the facts concerning Wolff’s actual facilities used to sell VAGISAN products in the United States are unknown. *See* Thevessen Dec. Dated Jan. 22, 2018, ¶ 13.

Similarity of the Goods. Combe claims that because in the TTAB proceeding Wolff expressed an intent to use the VAGISAN mark for a non-prescription, over-the-counter vaginal care cream, “Wolff’s product is clear and can be compared to Combe’s.” ECF No. 28 at 24. Combe’s argument is wrong because Wolff will defer any decision on the nature of the products sold in the U.S. until the TTAB appeal is resolved. *See* Thevessen Dec. Dated Jan. 22, 2018, ¶ 12. Moreover, the Court cannot presume that the parties’ respective products will be similar. *See Carefirst of Md.*, 434 F.3d at 272 (“As with the similarity of the marks, we measure the similarity of services with respect to each party’s actual performance in the marketplace.”).

Similarity of the Marks. Combe baselessly asserts that this factor is ripe for adjudication because “the factfinder can analyze the marks’ similarity, especially taking into account that consumers will often encounter the marks in a conversation or in plain letters (e.g., in print or online reviews) without the aid of packaging, stylization, or logos.” ECF No. 28 at 23. There is no evidence to suggest this is how consumers will “often encounter” the VAGISAN mark, as the mark may more frequently be displayed in a stylized format, in a color, or with distinctive design elements or additional wording. And the Fourth Circuit emphasizes that “[t]o determine whether two marks are similar, ‘we must examine the allegedly infringing use *in the context in which it is seen by the ordinary consumer.*’” *Carefirst of Md., Inc.*, 434 F.3d at 271 (emphasis added) (quoting *Anheuser-Busch, Inc. v. L & L Wings, Inc.*, 962 F.2d 316, 319 4th Cir. 1992). In this

regard, “because the likelihood-of-confusion analysis looks to the actual use of competing marks, a comparison of the texts of the two marks alone is insufficient if the marks have different appearances in the marketplace.” *Id.*; *Teal Bay Alls., LLC v. Southbound One, Inc.*, Civ. A. No. MJG-13-2180, 2015 WL 401251, at *14 (D. Md. Jan. 26, 2015) (“Whether the similarity in the use of the word ‘shorebilly’ is confusing is based upon how the marks are actually used in the marketplace.”). For example, “[i]f one of two similar marks is commonly paired with other material, that pairing will serve to lessen any confusion that might otherwise be caused by the textual similarity between the two marks.” *Carefirst of Md., Inc.*, 434 F.3d at 271. Accordingly, because Wolff’s VAGISAN mark has never been used in U.S. commerce, the Court does not have the necessary facts to analyze the issue of the similarity of the parties’ marks **as used in U.S. commerce**.

Actual confusion. To analyze the issue of actual confusion the defendant must have actually used its mark in the United States. While proof of actual confusion may not be necessary, the absence of such evidence would be highly relevant to Wolff’s defense in an infringement action. Deciding an infringement claim against Wolff before sales have begun, would deprive Wolff of the opportunity to present such evidence.

The quality of the defendant’s product. The quality of Wolff’s product as sold in the United States is unknown because the product is not yet available in the United States. The Court cannot presume that Wolff’s product will be of a particular level of quality.

Accordingly, the likelihood-of-confusion factors are not ripe for adjudication and it would be unjust to force Wolff to litigate those claims when the relevant evidence does not exist. Moreover, and contrary to Combe’s contention, it would be a waste of judicial resources to adjudicate the infringement and unfair competition claims at this point. If the Court were to

decide claims of infringement or unfair competition prematurely, Wolff would be denied the opportunity to present all facts needed to defend itself properly. Moreover, the Court would leave open the possibility that these claims would need to be re-litigated in the future, when and if all of the relevant facts become available. Combe incorrectly cites *Bertolli* for the proposition that “equity and common sense dictate the issuance of an injunction at this early stage, before defendant[] ha[s] needlessly devoted time, energy and financial resources to a futile endeavor.” ECF No. 28 at 26 (citing *Bertolli USA, Inc. v. Filippo Bertolli Fine Foods, Ltd.*, 662 F. Supp. 203, 205-06 (S.D.N.Y. 1987)). Combe omits to mention the critical fact that the *Bertolli* court granted an injunction only after finding that the defendant’s goods had been “**transported**” in U.S. commerce and that the defendant had engaged in other significant activities in the U.S. *Id.* at 205.⁸ Here, by contrast, Combe has not and cannot plead that Wolff has not sold, advertised or transported any goods in commerce.

CONCLUSION

For the foregoing reasons, Counts II–VI of Combe’s Complaint should be dismissed pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure because Combe has failed to state a claim on which relief can be granted.

⁸ In evaluating whether the “in commerce” requirement had been met, the *Bertolli* court noted that the statute states that use in commerce occurs when a mark is sold, advertised or transported in commerce. *Id.* at 205 The court granted the injunction only after finding that to meet the definition of “use in commerce” “it is sufficient that the goods be transported in commerce. 15 U.S.C. § 1127. Defendants’ actions - including sending one bottle of olive oil to a distributor in San Francisco and offering the product to another distributor in New York, plus their activities of printing labels and cartons - are sufficient to meet the ‘use in commerce’ test.” *Id.*

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 22nd day of January, 2018, I will electronically file the foregoing with the Clerk of Court using the CM/ECF system, which will then send a notification of such filing (NEF) to the following:

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